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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,395	04/13/2006	Keiji Igaki	113184-115	8599

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EXAMINER	
DORNBUSCH, DIANNE	
ART UNIT	PAPER NUMBER
3773	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,395	IGAKI, KEIJI	
	Examiner	Art Unit	
	DIANNE DORNBUSCH	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 13 recites that the stent is not exposed by the tearing assisting portion, this is considered new matter since the original disclosure does not specify this limitation.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armstrong et al. (6,899,727) in view of Karpiel (2004/0010265) and further in view of Susawa et al. (5,591,222).

Claim 1:

Armstrong discloses a device (10) for delivery of a stent (12) for the vessel (20) comprising: a catheter (16) for insertion into the vessel (20) of a living body (Fig. 1); a balloon (15) mounted on an outer peripheral surface of the distal end side of said catheter (Fig. 1) and inflatable with a fluid supplied to said catheter (Fig. 1-1B); a stent (12) for the vessel mounted on said balloon in a diameter-contracted state (Fig. 1A and Col. 6 Lines 32-38), said stent having self-expanding properties (Col. 3 Lines 1-5 and Col. 6 Lines 47-48); and a stent holding member (11) formed of a polymer material (Col. 3 Lines 3-6) to a tube form (Fig. 1) for holding said stent for the vessel on said balloon (Fig. 1 and Col. 3 Lines 3-6), and configured for covering at least a portion of said stent for the vessel from said catheter (Fig. 1 and 6A); said stent holding member having been drawn in the longitudinal direction (Fig. 1-1B) and being provided with a tearing assisting portion (19) at a distal end thereof located towards the distal end of said catheter (Fig. 1, 5, 6, 11).

Armstrong teaches all the claimed limitations discussed above including that the polymer material of the stent holding member is PTFE (Col. 3 Line 6) however, Armstrong does not specify that the polymer material has polymer molecules oriented in the longitudinal direction.

Karpiel discloses a stent deliver device with a stent holding means (50) that tears along the longitudinal axis (Fig. 4) wherein the stent holding means is made of a polymer such as PTFE which contains molecules oriented along the longitudinal axis as disclosed in [0021].

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Armstrong polymer molecules oriented in the longitudinal direction in view of the teachings of Karpiel, since the molecular properties permit it to be torn longitudinally along a predetermined split line.

Armstrong in view of Karpiel teaches all the claimed limitations discussed above however, Armstrong in view of Karpiel does not disclose that the stent is formed of a biodegradable polymer

Susawa discloses said stent (1) being formed of a biodegradable polymer (Col. 2 Lines 59-61).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Armstrong in view of Karpiel with a biodegradable stent in view of the teachings of Susawa, in order to provide a stent that would not have to be later removed from the body after vessel repair. Further, the combination would have merely required a substitution of one stent for another. It has been held that the substitution of one known element for another to yield predictable results requires only routine skill in the art.

Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a biodegradable material on the stent, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 2: Armstrong discloses that said tearing assisting portion is a slit (each perforation 19 is a slit as seen in Fig. 1, 5, 6) provided to the distal end side of said stent holding member (Fig. 1).

Armstrong discloses all the limitations discussed above, however Armstrong does not specify that the slits are v-shaped.

Karpiel discloses a v-shaped slit as seen in Fig. 4. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Armstrong with a v-shaped slit since it is an obvious change in shape where the instrument will still have the same functionality In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (MPEP 2144.04).

Claim 3: Armstrong discloses that the distal end of said tearing assisting portion is closed by a connecting portion (Fig. 1, 5, 6).

Claim 4: Armstrong discloses that said tearing assisting portion is a slit formed for extending along the longitudinal direction of said stent holding member (Fig. 1, 5, 6).

Claim 5: Armstrong discloses that said stent holding member is formed of PTFE (polytetrafluoroethylene) (Col. 3 Line 6).

Claim 6: Armstrong discloses that the proximal side of said stent holding member, located on said catheter, is secured to said catheter (Col. 4 Lines 60-65).

Claim 7: Armstrong discloses that an air-vent through-hole is bored in the proximal side of said stent holding member secured to said catheter (Fig. 1-2 where the stent holding member has a lumen/bore through its center where the stent is located).

Claim 8: Armstrong discloses that said stent holding member covers up the entire length of said stent for the vessel (Fig. 1, 5, 6).

Claim 9: Armstrong discloses that the distal end of said stent holding member, provided with said tearing assisting portion, is contracted in diameter so as to be tightly contacted with said balloon (Fig. 1, 5, 6 where it is contracted when assembled prior to delivery).

Claim 10: Armstrong discloses that said stent holding member is connected to a yarn (111) passed through said catheter so as to be pulled out partway from said catheter, and wherein said stent holding member may be released from the stent for the vessel by pulling said yam outward from said catheter (Fig. 11 and Col. 9 Lines 45-64).

Claim 11:

Armstrong teaches all the claimed limitations discussed above however, Armstrong does not disclose that the stent is formed of a yarn of a biodegradable polymer to a tube form.

Susawa discloses said stent (1) being formed of a yarn of biodegradable polymer (Col. 2 Lines 42-61).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Armstrong with a yarn of a biodegradable polymer to form the stent in view of the teachings of Susawa, in order to provide a stent that would not have to be later removed from the body after vessel repair. Further, the combination would have merely required a substitution of one stent for another. It has been held that the substitution of one known element for another to yield predictable results requires only routine skill in the art.

Additionally, i would have been obvious to one having ordinary skill in the art at the time the invention was made to use a biodegradable material on the stent, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Note that the claimed phrase "formed of a yarn biodegradable polymer to a tube form" is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113.

Claim 12: Armstrong discloses that said tearing assisting portion is an incision provided at the distal end of said stent holding member (Fig. 1, 5, 11, and 12).

Claim 13:

Armstrong discloses all the limitations discussed above including that said tearing assisting portion extends in the longitudinal direction from the distal end of the stent holding member (Fig, 1, 5, 11, and 12)/ However, Armstrong does not specify that the stent holding member to a point prior to reaching said stent for the vessel such that the stent for the vessel is not exposed by the tearing assisting portion.

Kalier discloses a that the stent cover can longer than the length of the stent as well as the tearing assisting portion being spaced apart from the stent.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the stent cover longer, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made have the slits spaced away from the stent, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Response to Arguments

5. Applicant's arguments with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773